

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

**CONFIDENTIAL
FILED UNDER SEAL**

**SMITH & NEPHEW'S REPLY BRIEF IN SUPPORT
OF ITS INEQUITABLE CONDUCT CASE**

Dated: July 24, 2003

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I. INTRODUCTION

There has been a significant new development since Smith & Nephew filed its Opening Inequitable Conduct Brief (D.I. 442). In late June and early July, the United States Patent and Trademark Office ("PTO") granted Smith & Nephew's requests to reexamine all three of the patents-in-suit. (See Exs. A, B, and C attached to the Declaration of Keith A. Walter, Jr. in Support of Smith & Nephew's Reply Brief in Support of its Inequitable Conduct Defense, hereafter "Walter Dec. Ex. ____").

In granting these reexaminations, the PTO made several significant statements confirming the materiality of the information withheld by ArthroCare. For example, the PTO said that (1) claim 1 of the Roos '198 patent discloses electrically conductive fluid; (2) the electrically conductive fluid disclosure was overlooked by the previous examiners; and (3) Smith & Nephew's arguments (from Smith & Nephew's summary judgment briefs and expert reports) and the Roos Declaration presented the Roos '198 patent in a "new light," which raised substantial new questions as to the patentability (*i.e.*, validity) of the patents-in-suit.

II. SUMMARY OF ARGUMENT

ArthroCare has shown a pattern of behavior in its prosecution of the patents-in-suit that violates the uncompromising duty of candor it owes to the PTO. It should not be rewarded with enforceable patents. ArthroCare's pattern includes:

- During the prosecution of the '592 patent, John Raffle, ArthroCare's patent attorney, argued that the Roos '198 patent *did not* disclose electrically conductive fluid, but he withheld a decision from a district court that held that Roos '198 *did* disclose electrically conductive fluid. As the court in *Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc.*, 53 U.S.P.Q.2d 1302 (N.D. Ill. 1999), held, the materiality of the district court decision "lies in [the judge's] own determination that the recited prior art was sufficient to overcome the statutory presumption of validity. This determination is material in its own right." *Id.* at 1331
- Also during the prosecution of the '592 patent, Mr. Raffle argued that the Roos '667 patent supported his arguments about the Roos '198 patent, but withheld the district court decision that rejected that argument.
- During the reexamination of the '536 patent, Mr. Raffle withheld Smith & Nephew's summary judgment and expert report arguments on validity, as well as

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the evidence in the Roos declaration, which the PTO has now said present the prior art "in a new light," thus raising a substantial new question of patentability.

- During the prosecution of the '882 patent, Mr. Raffle did not tell the PTO that the "corrections" he was making broadened the scope of the patent, but in trial even ArthroCare's paid expert witness admitted that they did broaden the patent.

In its Opposition, ArthroCare has raised many excuses in an attempt to justify its conduct in the PTO—such as calling Mr. Raffle "sloppy." None of these excuses has any merit. Indeed, many appear to be nothing more than an attempt to confuse the Court with respect to the legal distinctions between patent litigation in the courts and patent prosecution in the PTO.

Mr. Raffle's hide-the-ball approach to obtaining the patents in suit is not the approach of a "reputable lawyer" deserving "respect for [his] integrity" as a member of an honorable profession, and does not "sustain the good name of the bar itself." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Smith & Nephew's charge is not a "plague," *id.*; it is an exhortation to this Court that ArthroCare's behavior in the PTO should not be countenanced.

III. ARGUMENT

A. The Evidence of ArthroCare's Inequitable Conduct

ArthroCare spends the first five pages of its argument pleading hyper-technical evidentiary arguments in an attempt to dissuade the Court from considering the overwhelming evidence of ArthroCare's violation of its duty of candor to the PTO. ArthroCare cites caselaw that turns on unfair surprise and prejudice, but describes no unfair surprise or prejudice that it has suffered. And it tries to parse its inequitable conduct into thin slivers in an attempt to have the Court ignore each of the slivers, when it is ArthroCare's pattern of inequitable behavior that should be the focus. The Court should reject ArthroCare's invitation to stick its head in the sand and ignore ArthroCare's repeated breaches of the utmost duty of candor owed to the PTO during the *ex parte* prosecution of a patent application.

ArthroCare's hyper-technical evidentiary arguments are unavailing in any event. One of ArthroCare's arguments is that Smith & Nephew should not be able to refer to *the very evidence that Smith & Nephew pled* as the basis for its inequitable conduct claim. That evidence is

already before the Court and has already been considered by the Court. ArthroCare was well-aware of the evidence, and suffers no unfair surprise or prejudice by Smith & Nephew's reliance on it. ArthroCare's request to exclude this evidence should be rejected.

For example, ArthroCare asserts that the Court should ignore Judge Orrick's Memorandum and Order of December 1, 1998 ("Orrick opinion," Ex. D attached to the Declaration of William J. Marsden In Support of Smith & Nephew's Opening Brief, D.I. 443) from the prior *ArthroCare v. Ethicon* case because it was not presented to the jury. But the Orrick opinion was cited in Smith & Nephew's initial counterclaim in support of the inequitable conduct defense relating to the '592 patent. (D.I. 10 at 7-9). Certainly ArthroCare cannot complain of any surprise or unfairness over the fact that Smith & Nephew has relied on the very document it pled at the outset of this case. Moreover, the Court has previously considered the Orrick opinion several times (e.g., D.I. 49, 321, 339). Thus, there is no "last minute production of evidence" as in *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 550-51 (Fed. Cir. 1998), and there is no sound reason for the Court to ignore ArthroCare's failure to adequately disclose the Orrick opinion to the PTO.

ArthroCare also argues that the Court should disregard its failure to disclose Smith & Nephew's summary judgment briefs, its experts' reports on invalidity, and the Roos Declaration in the '536 reexamination. But again, ArthroCare is trying to exclude evidence that formed the basis for the inequitable conduct charge *when the charge was pled*. There is no surprise and no prejudice to ArthroCare. The inequitable conduct charges for the '536 reexamination were added to the case during the pretrial conference on April 15, 2003 (See D.I. 371 at 21-22, 42-43). At that time, Smith & Nephew explained that the basis for the charge was spelled out in its Second Supplemental Response to Interrogatory No. 6, which explained ArthroCare's failure to submit Smith & Nephew's summary judgment briefs and experts' reports to the PTO. (Walter Dec. Ex. D). The Roos Declaration is an exhibit to both the invalidity summary judgment brief (see D.I. 267 at Ex. 8), and Dr. Taylor's expert report (see D.I. 263 at Ex. 1, Tab 20). Again, ArthroCare can claim no surprise or unfairness at the consideration of this material, which has also previously

been analyzed by the Court (e.g., D.I. 49, 321, 339). Thus, ArthroCare's request to disregard this clearly relevant evidence should be denied.

B. ArthroCare's Inequitable Conduct During the '592 Prosecution

Turning to the substantive arguments, ArthroCare committed inequitable conduct in the prosecution of the '592 patent with its arguments that the Roos '198 patent does not disclose electrically conductive fluid. It made these arguments knowing that Judge Orrick in the prior *Ethicon* case had specifically found Roos '198 did disclose electrically conductive fluid. ArthroCare made misleading arguments about other references, without bothering to discuss the Orrick opinion or the Elsässer and Roos article, both of which contradicted ArthroCare's arguments. (D.I. 442 at 10-11). In its Opposition, ArthroCare has made several excuses for its behavior. None has merit.

1. Smith & Nephew's Inequitable Conduct Defense is Proper

ArthroCare tries to dodge its inequitable conduct, by claiming that each piece of evidence was not properly pled. But Smith & Nephew asserted its inequitable conduct defense related to the '592 patent when it filed its Answer and Counterclaims on September 13, 2001. (D.I. 10 at 7-9, ¶¶ 15-26). In its opposition, ArthroCare tries to argue that this defense consisted of many different and unrelated defenses, by breaking it into multiple pieces, arguing that each set of facts relates to a different defense. (See D.I. 462 at 4). This is simply wrong. Smith & Nephew's defense is based upon ArthroCare's arguments to the PTO that are contrary to the Orrick opinion and ArthroCare's failure to properly disclose that opinion to the PTO.¹

Smith & Nephew has, in its Opening Brief, simply provided more detailed arguments to support its inequitable conduct case. There is "nothing about the particularized pleading requirement [that] acts as a bar to further supplementing those facts, as they are uncovered."

¹ Judge Orrick's rejection of ArthroCare's arguments about the Roos '667 patent, the Roos '198 patent, and the Elsässer and Ross article are at pages 16-17 of his opinion. Thus, contrary to ArthroCare's argument (D.I. 462 at 5), these are not "new allegations." Moreover, all of this was known to Mr. Raffle, who was undisputedly aware of the Orrick opinion.

Agere Systems Guardian Corp. v. Proxim, Inc., 190 F. Supp. 2d 726, 734 (D. Del. 2002).² Nor can ArthroCare show that it was surprised, disadvantaged, or substantially prejudiced, since it has long known about the Orrick opinion and its failure to submit it to the PTO. Moreover, everything that ArthroCare did and did not say to the PTO about the Orrick opinion is already of record in the '592 file history. (DTX 300).

ArthroCare's only attempt to show prejudice is its claim that it did not have an opportunity to introduce evidence at trial to rebut the facts related to ArthroCare's non-disclosure of the Orrick opinion. Yet it points to no actual rebuttal evidence that it would have presented. Indeed, its only rebuttal to the inequitable conduct charge is that the "existence" of the Orrick opinion was disclosed as part of a list of 84 items in an IDS during prosecution. (See D.I. 462 at 12-22). It does not dispute the fact that the Orrick opinion itself was not provided to the PTO. Also, ArthroCare had the opportunity to fully cross-examine Mr. Raffle on any issues Smith & Nephew asked him about during trial. See *Craft v. U.S.*, 233 F.3d 358, 372 (6th Cir. 2000) (finding that plaintiff failed to show how she would be prejudiced by defendant's amendment to pleadings, conforming to new evidence, where plaintiff had not been prohibited from cross-examining defendant's witnesses on the amended issue), *rev'd on other grounds, United States v. Craft*, 535 U.S. 274 (2002); see also *Clemco Industries v. Commercial Union Ins. Co.*, 665 F. Supp 816, 830 (N.D. Cal. 1987) (finding that plaintiff's cross examination of defendant's witnesses afforded it a fair opportunity for rebuttal and that plaintiff had therefore not been prejudiced according to Rule 15(b)).

ArthroCare also argues that Smith & Nephew should not be allowed to rely on the Orrick opinion because it is not in the trial record. (D.I. 462 at 19). However, as discussed above, it is indeed part of the inequitable conduct record because it was cited in Smith & Nephew's pleadings

² Further, as ArthroCare itself admits, even completely new theories, which these are not, should only be excluded when the opposing party would be surprised, disadvantaged or substantially prejudiced. (D.I. 462 at 6-7). As *Commissioner v. Transport Mfg. & Equipment Co.*, 478 F.2d 731, 736 (8th Cir. 1973), a case cited by ArthroCare, holds, a party does not "necessarily lose[] his right to pursue a theory...that is not specifically raised before or at trial. The basic consideration is whether the [other party] is surprised and disadvantaged when the" party failed to plead the defense.

on the issue. (D.I. 10 at 7-9). Moreover, as pointed out repeatedly by ArthroCare, the *existence* of the Orrick opinion is "disclosed" in the '592 prosecution history. (DTX 300, October 25, 1999 IDS), which is in the trial record. Further, in sharp contrast to the situation in *ATD Corp.*, 159 F.3d at 550-51, ArthroCare was fully aware of Smith & Nephew's reliance on this opinion long before trial, and can claim no unfair surprise or prejudice. In fact, ArthroCare recognized the relevance of the Orrick opinion to the inequitable conduct case in its Motion *in Limine* to exclude the opinion from trial, where it argued that the Orrick opinion should not be presented to the jury because it was only relevant to the inequitable conduct case. (See D.I. 321 at n. 3).³ Thus, the Court should consider the contents of the opinion, which it has previously considered (D.I. 49, 367), in its analysis of the inequitable conduct claim.

2. ArthroCare's Intent to Deceive the PTO

ArthroCare withheld this material information with the intent to deceive the PTO. In most cases, including here, intent to deceive is not proven with direct evidence, but rather is inferred from circumstantial evidence. *Paragon Podiatry Lab, Inc. v. KLM Labs., Inc.* 984 F.2d 1182, 1189-90 (Fed. Cir. 1993); see also *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989); *LaBounty Mfg., Inc. v. U.S. Intern. Trade Com'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Direct proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances."); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed. Cir. 1991); *Critikon Inc. v. Becton Dickinson Vascular Access Inc.*, 28 U.S.P.Q. 2d 1362, 1370 n.2 (D. Del. 1993) ("Because direct evidence of an intent to deceive rarely exists, the Court may rely on circumstantial evidence leading to an inference of intent to mislead as the basis for a finding of inequitable conduct."); *Molins PLC v. Textron, Inc.*, 821 F. Supp. 1551, 1566 (D. Del. 1992); *Carroll Touch Inc. v. Electro Mechanical Systems Inc.*, 24 U.S.P.Q. 2d 1349, 1353 (C.D. Ill. 1992) ("Deliberate conduct can be inferred from the fact that the applicant had knowledge of the material

³ The motion *in limine* was granted. However, to the extent this Court may have previously questioned the relevance of the Orrick opinion as noted by ArthroCare (D.I. 462 at

information.”), *aff’d in part & vacated in part*, 15 F.3d 1573 (Fed. Cir. 1993).⁴ And here, ArthroCare’s intent to deceive the PTO is shown clearly and convincingly by the circumstances surrounding ArthroCare’s withholding of the material information.

In particular, the element of intent to deceive can be inferred from knowledge of the material information coupled with knowledge of the duty of disclosure. *LaBounty Mfg., Inc.*, 958 F.2d at 1076; *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1240 (Fed. Cir. 2003) (“The determinations that Mr. Pilard knew of the significance of the [withheld information] in combination with the finding that he knew of the duty to disclose is sufficient to establish intent”) In our Opening Brief, we showed that Mr. Raffle was aware of the Orrick opinion as well as his duty of disclosure as set forth in M.P.E.P. 2001.06(c). ArthroCare has not disputed either fact.

ArthroCare’s intent to deceive the PTO can also be inferred from additional circumstantial evidence. Mr. Raffle provided the PTO with a list of materials from the Ethicon case “that reflected the parties’ primary invalidity and enforceability arguments.” (D.I. 462 at 12-13).⁵ But The Orrick opinion does far more than merely reflect “the parties’ primary invalidity and enforceability arguments”; it *outright rejects ArthroCare’s validity arguments*. Thus, the description of the Orrick opinion by Mr. Raffle is misleading. At a minimum, the patentee is required to describe the nature of the litigation materials. *Marlow Indus. v. Igloo Prods. Corp.*, 2002 WL 485698, at *4 (N.D. Tex. Mar. 28, 2002) (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1259 (Fed. Cir. 1997)).⁶ Mr. Raffle described the Orrick

19), that was in relation to Smith & Nephew’s defense of patent misuse, not in relation to its inequitable conduct defense.

⁴ ArthroCare’s reliance on *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987) and *Fuji Photo Film Co. v. Jazz Photo Corp.*, 173 F. Supp. 2d 268, 276 (D. N.J. 2001) is misplaced. In both these cases, the improper inference of intent stemmed from a single fact. Here, an extensive series of facts and circumstances demonstrates ArthroCare’s intent.

⁵ ArthroCare, trying to rebut the inference that Mr. Raffle buried the Orrick opinion in a long list of litigation related documents, says that the *Ethicon* litigation documents were listed in chronological order. (D.I. 462 at 18, n. 10). This is not true, as can readily be seen from the list. (DTX 300, October 25, 1999 IDS at pp. 3-8).

⁶ ArthroCare attempts to distinguish *Marlow Indus.* because in that case the patentee did not disclose the court’s claim construction at all. ArthroCare’s misleading characterization of the material Orrick opinion, in a misleadingly labeled list, is hardly less culpable.

opinion simply as a "Memorandum Decision and Order Regarding Preliminary Injunction Motion, issued December 2, 1998." (DTX 300, October 25, 1999 IDS at p. 5). While this description may be technically accurate, it is plainly misleading since it fails to inform the PTO that (1) the preliminary injunction was denied, (2) it was denied in light of adverse findings of fact regarding the validity of ArthroCare's patents, and (3) those fact findings were directly contrary to the arguments ArthroCare was making to the PTO.

ArthroCare's various arguments to overcome the examiner's rejections based on the Roos '198 patent provide additional evidence of its intent to deceive. (See D.I. 442 at 11-12). While ArthroCare could have tried to distinguish Judge Orrick's finding that the Roos '198 patent disclosed electrically conductive fluid, it was still required to disclose the Orrick opinion to the examiner in a manner that would apprise the examiner of its relevance. The intent does not stem from ArthroCare arguing against the findings in the Orrick opinion, but rather that it argued against Judge Orrick's findings *without even telling the PTO about them and allowing the PTO to take those findings into consideration.*

Finally, intent is more easily inferred when the reference is highly material. "[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances." *Critikon, Inc.*, 120 F.3d at 1257. ArthroCare has not shown any subjective good faith that would overcome its failure to sufficiently disclose the Orrick opinion.

3. The Orrick Opinion is Highly Material

There can be no dispute that the Orrick opinion is highly material. Information is material when "[i]t refutes, or is inconsistent with, a position the applicant takes in (i) Opposing an argument of unpatentability relied on by the [Patent] Office, or (ii) Asserting an argument of patentability." 37 C.F.R. § 1.56(b)(i)-(ii). ArthroCare does not dispute that the Orrick opinion is

inconsistent with its positions taken in opposing the examiner's rejection based on the Roos '198 patent.

ArthroCare throws up several red herrings in an attempt to downplay the Orrick opinion's significance. First, it argues that the Orrick opinion is not material because the evidence at trial and the examiner's allowance established that the Roos '198 patent does not disclose electrically conductive fluid. This is not correct⁷ and, in any event, is not relevant. A reference does not have to actually render a patent invalid to be material. See *A.B. Dick v. Burroughs Corp.*, 798 F.2d 1392, 1392, 1400 (Fed. Cir. 1986) (affirming the district court's finding of inequitable conduct even though district court has also found the patents valid and infringed.); see also *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1237 (Fed. Cir. 2003); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed. Cir. 2000); *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421, (Fed. Cir. 1989); *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1214 (Fed. Cir. 1987); *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 910 F.2d 804, 812 (Fed. Cir. 1990); *RCA Corp. v. Data General Corp.* 701 F. Supp. 456, 474 (D. Del. 1988), *aff'd*, 887 F.2d 1056 (Fed. Cir. 1989).

ArthroCare's Roos '198 arguments constituted inequitable conduct because it knew that those arguments were directly contrary to the Orrick opinion and yet it failed to adequately disclose the Orrick opinion to the examiner. 37 C.F.R. § 1.56(b)(i)-(ii). The rules require that ArthroCare provide enough information "to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation." MPEP 2001.06(c). Providing a misleading, over-simplified description of the Orrick opinion certainly does not meet this requirement. See also 37 C.F.R. § 1.98(a)(2)(iv) (an IDS must include a legible copy of "all other information or that portion which caused it to be listed" in the IDS); *Critikon, Inc.*, 120 F.3d at 1258-59.

⁷ As more fully discussed in Smith & Nephew's Motion for Judgment as a Matter of Law, ArthroCare never rebutted Smith & Nephew's clear and convincing evidence that the Roos '198 patent discloses electrically conductive fluid. (See D.I. 459).

In *Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc.*, 53

U.S.P.Q.2d 1302 (N.D. Ill. 1999), the court rejected a "no-materiality" argument substantially identical to that put forth by ArthroCare:⁸

Plaintiffs argued that the 'substance' of the order [denying the preliminary injunction] was fully disclosed, since each of the prior art references cited therein was before the examiner. This argument ignores the significance of the order, which goes far beyond its recitations of prior art; *its significance lies in [the judge's] own determination that the recited prior art was sufficient to overcome the statutory presumption of validity. This determination is material in its own right, and was never submitted or disclosed to the examiner.*

Id. at 1331 (emphasis added). Likewise, here, the Orrick opinion "is material in its own right."

Thus, no matter what the jury verdict and the examiner's allowance indicates to ArthroCare, the legal requirement was for ArthroCare to disclose to the examiner Judge Orrick's detailed findings that the Roos '198 patent does indeed disclose electrically conductive fluid.⁹

ArthroCare also argues the Orrick opinion is immaterial because Smith & Nephew did not assert the Roos '198 patent or the Elsässer and Roos Article in its invalidity case against the '592 patent during trial. But Smith & Nephew's decision to streamline its case in view of the limited trial time does not take away from the materiality of the Orrick opinion or the actual disclosure of the Roos '198 patent or the Elsässer and Roos Article as invalidating art. As we pointed out in our Opening Brief, the Court is obliged to independently assess the materiality of these references, irrespective of the jury verdict. (D.I. 442 at 18-19).

⁸ The Federal Circuit affirmed the finding that the PI Order was material but overruled the overall inequitable conduct finding of the district court on other grounds. *Newell Window Furnishings, Inc. v. Spring Window Fashions Division, Inc.*, 15 Fed. Appx. 836, 839, 2001 WL 744460 (Fed. Cir. 2001) (non-precedential opinion).

⁹ Astoundingly, ArthroCare continues to misrepresent what claim 1 of the Roos '198 patent discloses. In its Answering brief (D.I. 462 at 15), ArthroCare "quotes" claim 1 of the Roos '198 patent as "provide[s] electrical conductance." *Id.* It attempts to use this paraphrasing to support its bizarre position that all liquids conduct electricity and that claim 1 therefore discloses non-conductive liquid. ArthroCare's selective quotation is very different from the actual language "liquid to provide electrical conductance between said electrodes." (DTX-11 at col. 7, lines 61-62). If the whole purpose of adding a liquid is to "provide electrical conductance," how can it possibly be consistent with the disclosure being of a non-conductive liquid?

Moreover, the materiality of the Roos '198 patent and the Elsässer and Roos Article has been reaffirmed by the PTO. In granting reexamination of the '592 patent, the PTO explained:

As pointed out on page 2 of the request, Roos '198 *discloses an electrically conducting fluid in claim 1. The teaching of an electrically conducting fluid by Roos '198 was not considered in the prosecution of the application*, which became the Eggers et al. patent. ... Accordingly Roos '198 raises a substantial new question of patentability ... which question has not been decided in a previous examination of the Eggers et al. patent.

Furthermore, as pointed out on page 5 of the request the Elsässer and Roos article discloses current flowing from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid. The teaching of the irrigation liquid being conductive by the Elsässer and Roos article was not considered in the prosecution of the application, which became the Eggers et al. patent.

In addition, the examiner finds that the Roos '198 prior art, which was already considered by the examiner in the prosecution of the Eggers et al. patent, is presented in a new light with respect to the washing fluid being conductive. ... *This teaching was not pointed out in the [prosecution of the] Eggers et al. patent, and apparently not recognized by the examiner.*

(Walter Dec. Ex. C at 2-4) (emphasis added).

Finally, ArthroCare argues that government officials are presumed to have properly done their job. (D.I. 462 at 14). This argument is unavailing. First, the Orrick opinion was not properly in front of the PTO. Thus, the examiner could not have properly performed his duty because he had no idea that Judge Orrick had found that the Roos '198 patent disclosed electrically conductive fluid. See MPEP 2001.06(c). This was not the examiner's fault, but rather the result of ArthroCare's intentional decision to characterize the opinion in a misleading way. Second, this presumption is not absolute. See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-1360 (Fed. Cir. 1984) (noting that parties may overcome deference granted to examiners who are presumed to have done their jobs); see also *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (noting that party may offer proof to counter assumption that examiner considered references). If the presumption were absolute, no patent could ever be found invalid or unenforceable through litigation or reexamination.

C. ArthroCare's Inequitable Conduct During the '882 Prosecution

ArthroCare committed inequitable conduct in the prosecution of the '882 patent by making affirmative misrepresentations to the PTO when it applied for a Certificate of Correction and failed to explain that the "corrections" would broaden the claims. (D.I. 442 at 28-29). In its Opposition, ArthroCare has raised several excuses and arguments. Again, none have merit.

1. Smith & Nephew's Allegation of Inequitable Conduct with Respect to the '882 Patent is Proper

Smith & Nephew's inequitable conduct defense related to the prosecution of the '882 patent arises out of evidence brought out at trial. Federal Rule of Civil Procedure 15(b) specifically allows the pleadings to be freely amended "as may be necessary to cause them to conform to the evidence and ... may be made upon motion of any party at any time, even after judgment." Fed. R. Civ. P. 15(b). The Rule further allows the Court to "grant a continuance to enable the objecting party to meet such evidence." *Id.*

As explained more fully in Smith & Nephew's Opening Brief, the testimony at trial, particularly of Mr. Raffle and Dr. Goldberg, provide the facts underlying this defense. The testimony included admissions directly contrary to arguments that ArthroCare had been making throughout the case. At trial, ArthroCare had ample opportunity to examine these witnesses on any testimony Smith & Nephew obtained from them. Further, ArthroCare had the opportunity to try to rebut Smith & Nephew's arguments made in its Opening Brief. Moreover, there was no "last-minute production of evidence" as in *ATD Corp.*, 159 F.3d at 550-51. Instead, there were only last-minute concessions at trial from ArthroCare's witnesses. Thus, ArthroCare can show no prejudice to it by allowing this defense. The Court should consider the defense and enter judgment that the '882 patent is unenforceable.

2. ArthroCare's Intent to Deceive the PTO

ArthroCare argues that Mr. Raffle's good faith is somehow proven by the fact that ArthroCare asserted claim 26 of the '882 patent in its lawsuit against Ethicon, without correcting the "three electrode" problem. (D.I. 462 at 35). ArthroCare further argues that "if Mr. Raffle were aware of the 'three electrode' problem in claim 52, he surely would have corrected it to

cover Ethicon's 'two electrode' products." This argument is misleading to the point of bordering on a violation of the ethical rules.¹⁰

There is absolutely no evidence in this case about claim 26 of the '882 patent being asserted against any "two electrode" products of Ethicon. Instead, the evidence is to the contrary. Based on documents produced to Smith & Nephew in discovery, claim 26 of the '882 patent was asserted against Ethicon products that had three separate electrodes.

ArthroCare's infringement allegations in the *Ethicon* case were raised in a preliminary injunction motion filed shortly after ArthroCare filed its lawsuit against Ethicon. The motion was supported by the declaration of ArthroCare's expert, William R. Dubrul, who explained the basis for ArthroCare's infringement contentions. With respect to claim 26 of the '882 patent, Mr. Dubrul explained:

As demonstrated in Exhibit I, the use of [Ethicon's] VAPR Systems involving the performance of each step recited in Claim 26. The VAPR Product Literature shows that the use of VAPR System involves providing an *active electrode* and a *return electrode* electrically coupled to a high frequency source, positioning the *electrode terminal* in close proximity to the target site in the presence of an electrically conductive fluid...

(Walter Dec. Ex. E) (emphasis added).

Thus, ArthroCare's supposed proof of Mr. Raffle's good faith vanishes. He did not seek a certificate of correction for claim 26 of the '882 patent because ArthroCare did not need one for its suit against Ethicon.

3. Mr. Raffle's Omissions and Misrepresentations are Material

Mr. Raffle's omissions and misrepresentations are material because they refute and contradict the arguments of patentability made by ArthroCare. 37 C.F.R. § 1.56(b)(i)-(ii).

ArthroCare never disputes that the statements made by Mr. Raffle were false, and that the changes made by the Certificate of Correction broaden the scope of the claims. In fact, its expert, Dr. Goldberg, admitted that the Certificate of Correction broadened the scope of claim 1 of the '882 patent. (Tr. 1109-11, D.I. 415). ArthroCare only argues that this does not matter because

¹⁰ ABA Model Rules of Prof'l Conduct R. 3.3(a)(1) requires that "a lawyer shall not knowingly...(3) offer evidence that the lawyer knows to be false."

the jury found the changes corrected typographical errors.¹¹ However, this argument once again confuses the legal standards that apply to patent litigation in the courts and those that apply to patent prosecution in the PTO. Mr. Raffle had a duty to tell the examiner that the changes broadened the scope of claim 1 because this information contradicts the Reasons for Allowance, which ArthroCare accepted. *Elkay Mfg. Co. v. Ebcu Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) (holding that failure to respond to an examiner's reason for allowance functioned as a disavowal of a different interpretation of the claim). Even though the examiner checked the box on the form saying that the changes would not materially affect the scope of the claims, "there is, of course, the possibility that mistakes were made or important information overlooked. Examiners have a lot of work to do and no process is perfect." (Tr. at 95, D.I. 409). Since it is now undisputed that the Certificate did broaden claims, there can be no dispute that the examiner made a mistake when he checked the box indicating that the changes would not materially affect the scope of the claims.

Similarly, ArthroCare argues that changing "active electrode" to "electrode terminal" cannot be material because these terms are used interchangeably. (D.I. 462 at 34). But any evidence of supposed interchangeability at trial is irrelevant to inequitable conduct during the prosecution of the '882 patent. Moreover, whether or not they are interchangeable terms, it is undisputed that the change reduced the number of electrodes that were required by the claim, and Mr. Raffle knew that when he sought those changes.

D. ArthroCare's Inequitable Conduct During the '536 Reexamination

ArthroCare committed inequitable conduct in connection with the reexamination of the '536 patent by failing to disclose Smith & Nephew's summary judgment briefs, experts' reports and the Roos Declaration, which all relate to the issues of invalidity. (D. I. 442 at 21-22). In its opposition, ArthroCare has raised several excuses and arguments. As we show below, none of these have merit either.

¹¹ However, as shown in Smith & Nephew's Motion for Judgment as a Matter of Law, the jury's verdict that the Certificate of Correction was valid was wrong as a matter of law because the changes were not of a typographical nature. (D.I. 459 at 14-15).

1. Smith & Nephew Has Properly Alleged New Inequitable Conduct Defenses

Once again, ArthroCare improperly attempts to break Smith & Nephew's inequitable conduct defense relating to the '536 patent into multiple separate defenses based on various discrete facts, and argues that the Court should consider only some of those separate pieces. (D.I. 462 at 5). But Smith & Nephew's defense is based upon ArthroCare's continued failure to provide material information from the present litigation to the PTO, despite the fact that it was contrary to the arguments ArthroCare was making.

Smith & Nephew should not be limited to the specific allegations in its pleadings for its inequitable conduct defense. *Agere Systems Guardian Corp.*, 190 F. Supp. 2d at 734. A pleading is not intended to be a summary judgment brief. Further, Smith & Nephew is not relying on any "last-minute production of evidence" (*cf. ATD Corp.*, 159 F.3d at 550-51), and ArthroCare has failed to prove that it would suffer any unfair surprise, disadvantage or prejudice.

Finally, ArthroCare argues that Smith & Nephew should not be allowed to rely on its experts' reports or the Roos Declaration because they are not in the record of the jury trial. However, they are properly within the scope of Smith & Nephew's pleading of its inequitable conduct defense, as discussed above. Moreover, the fact that ArthroCare never submitted those documents is clearly in the jury trial record:

Q. Finally, with respect to material that you did and did not submit to the Patent Office in connection with the re-exam, it is true, isn't it, that you did not submit Smith & Nephew's arguments about validity as set forth in its expert reports, Dr. Taylor's expert report, or in its summary judgment motions; right?

MR. BLUMENFELD: Objection, your Honor.

THE WITNESS: That's correct. We did not submit the expert reports in [sic: or] the summary judgment motions.

(Tr. at 1542, D.I. 417). In fact, this testimony was introduced on re-direct, after ArthroCare attempted to establish that Mr. Raffle had submitted Smith & Nephew's validity contentions to the PTO. (Tr. at 1535-36, D.I. 417). Moreover, since ArthroCare never disputes that the experts' reports and the Roos Declaration are inconsistent with its arguments to the PTO, materiality is established through that fact alone.

2. Evidence of Intent to Deceive the PTO

It is undisputed that ArthroCare did not provide the examiner with copies of Smith & Nephew's summary judgment briefs, its experts' reports or the Roos Declaration, each of which contradict ArthroCare's arguments. (*See supra*). It is from these facts that intent to deceive can be inferred. *Bristol-Myers Squibb*, 326 F.3d at 1240 ("the determination that Mr. Pilard knew of the significance of the [withheld information] in combination with the finding that he knew of the duty to disclose is sufficient to establish intent"). Further, ArthroCare has not shown any evidence of subjective good faith to overcome the high materiality of the Smith & Nephew litigation documents, as described below. *Critikon, Inc.*, 120 F.3d at 1257.

3. The Undisclosed Litigation Documents are Highly Material

The litigation documents that ArthroCare decided not to disclose to the PTO are highly material. Information is material when it is inconsistent with a position the applicant takes in opposing an argument of unpatentability. 37 C.F.R. § 1.56(b)(i). ArthroCare never disputes that Smith & Nephew's experts' reports and summary judgment briefs and the Roos Declaration are inconsistent with its positions taken in opposing the examiner's rejection based on the Roos '198 patent.

The materiality of these documents was recently confirmed by the PTO when it granted Smith & Nephew's requests for reexamination. (*See* Walter Dec. Exs. A, B and C). The reexamination requests included virtually all of the arguments made in Smith & Nephew's summary judgment briefs and experts' reports. In granting the reexamination, the examiner noted:

Requestor's argument concerning the interpretation of the limitation of claim 1 of Roos ('198) (Exhibit A) of liquid providing electrical conductance between electrodes presents the old art in a new light. The declaration of Eberhard Roos (Exhibit 1) also presents old art Roos ('198) and the Elsasser and Roos article in a new light.

(Walter Dec. Ex. A at 3). Thus, the PTO has found a substantial new question of patentability.

ArthroCare also argues that the Roos Declaration is immaterial as a matter of law.

However, once again, ArthroCare is confusing what is relevant or admissible in litigation and

rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application."'). This is particularly so where it is clear that ArthroCare's outside attorneys have long been involved in prosecution of ArthroCare's patents. For example, Smith & Nephew produced documents during discovery in this case to litigation counsel who then had ArthroCare submit them to the PTO (PTX 7 at 282-289). There is no reason that litigation counsel could not have also turned over the Roos Declaration and Smith & Nephew's experts' reports and summary judgment briefs for submission to the PTO. In fact, Mr. Raffle testified during his deposition that Mr. Bobrow, ArthroCare's lead litigation counsel, was involved in preparing the list of material to submit to the PTO from the Ethicon case in the course of the '592 prosecution. (Walter Dec. Ex. F, at 261-62). Certainly Mr. Bobrow knew about ArthroCare's duty of disclosure in this case as well.

Therefore, Smith & Nephew's summary judgment briefs, its experts' reports and the Roos Declaration are all material information that was not disclosed to the PTO, and ArthroCare's intent to deceive has not been rebutted by any showing of subjective good faith, proving that ArthroCare committed inequitable conduct during prosecution of the '536 reexamination. *Bristol-Myers-Squibb*, 326 F.3d at 1240.

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IV. CONCLUSION

For all of the foregoing reasons, as well as the reasons set forth in Smith & Nephew's Opening Brief, Smith & Nephew respectfully requests that the '536, '882, and '592 patents be held unenforceable due to inequitable conduct by ArthroCare in obtaining each of the patents.

Dated: July 24, 2003

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of July, 2003, a true and correct copy of SMITH & NEPHEW'S REPLY BRIEF IN SUPPORT OF ITS INEQUITABLE CONDUCT CASE was caused to be served on the attorneys of record at the following addresses as indicated:

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